

Patent
DPP-IV-5004-C2

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Jun Feng et al.

Serial No.: 10/809,637

Filed: March 24, 2004

For: DIPEPTIDYL PEPTIDASE
INHIBITORS



Group Art Unit: 1624

Examiner: Thomas C. McKenzie

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with 37 CFR §§ 1.97 and 1.98, the items identified in this Supplemental Information Disclosure Statement ("SIDS") are brought to the attention of the Office. The items are listed on the attached form PTO-1449, and copies of the literature and non-U.S. patent references are included

The items identified in this SIDS may or may not be "material" pursuant to 37 CFR § 1.56. The submission thereof by Applicant is not to be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR § 1.97(h)), or even qualifies as "prior art" under 35 USC § 102 with respect to this invention unless specifically designated by Applicants as such.

04/07/2006 HALI11 00000172 502256 1069637

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CERTIFICATE OF HAND DELIVERY

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being delivered via hand delivery to the Commissioner for Patents, Randolph Building, 401 Dulany Street, Alexandria, Virginia 22314.

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INFORMATION DISCLOSURE STATEMENT FILING PROVISION:

☐ This SIDS is believed to be timely in that it is being submitted under 37 CFR § 1.97(b), that is (1) within three months of the filing date of the application, which is not a continued prosecution application filed under § 1.53(d); or (2) within three months of entry of the national stage as set forth in 37 CFR § 1.491; or (3) before the mailing of a first Office action on the merits; or (4) before the mailing of a first Office action after filing a request for continued examination under § 1.114. Thus, no fee is required.

☐ However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this SIDS as filed under 37 CFR § 1.97(c), if applicable, and charge the fee due under 37 CFR § 1.17(p) to the deposit account referenced below.

☐ However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this SIDS as filed under 37 CFR § 1.97(c), if applicable, and a statement under 37 CFR § 1.97(e) is included below, thus no fee is required.

☒ This SIDS is being submitted under 37 CFR § 1.97(c), that is after mailing of a first Office action on the merits, but before a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311.

☒ The fee due under 37 CFR § 1.17(p) is submitted herewith.

☐ A statement under 37 CFR § 1.97(e) is included below, thus no fee is required. In the event that this SIDS is not received before a Final Action or a Notice of Allowance, then Applicant respectfully requests that the Office consider the filing of these papers to be submitted under 37 CFR § 1.97(d) and charge the fee due under 37 CFR § 1.17(p) to the deposit account below.

☐ This SIDS is being submitted under 37 CFR § 1.97(d), that is after a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311, but before payment of the issue fee. A statement under 37 CFR § 1.97(e) is included below. The fee due under 37 CFR § 1.17(p) is submitted herewith.

STATEMENT UNDER 37 CFR § 1.97(e):

☐ Each item contained in this SIDS was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this SIDS.

☐ No item contained in this SIDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person

signing this statement after making reasonable inquiry, no item of information contained in this SIDS was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this SIDS.

PAYMENT AND/OR AUTHORIZATION TO CHARGE FEES:


- ☐ A check in the amount of _____ is enclosed for the above fee(s).
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Although Applicants do not believe any additional fees are required, the Commissioner is authorized to charge any additional fees that may be required by the filing of these papers to Takeda's Deposit Account No. **50-2256**.

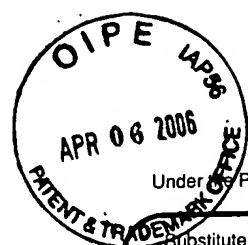
Respectfully submitted,

TAKEDA SAN DIEGO, INC.

Dated: 4/5/2006

By: 
Mitchell R. Brustein
Reg. No. 38,394

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PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 14

Complete if Known

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|------------------------|--------------------|
| Application Number | 10/809,637 |
| Filing Date | March 24, 2004 |
| First Named Inventor | Jun FENG |
| Group Art Unit | 1624 |
| Examiner Name | Thomas C. McKenzie |
| Attorney Docket Number | SYR-DPP-IV-5004-C2 |

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| | | First Named Inventor | Jun FENG | | |
| | | Group Art Unit | 1624 | | |
| | | Examiner Name | Thomas C. McKenzie | | |
| Sheet | 2 | of | 14 | Attorney Docket Number | SYR-DPP-IV-5004-C2 |

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| Sheet | 3 | of | 14 | Attorney Docket Number | SYR-DPP-IV-5004-C2 |

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| Sheet 4 of 14 | Attorney Docket Number | SYR-DPP-IV-5004-C2 | |

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| | | | Application Number | 10/809,637 | |
| | | | Filing Date | March 24, 2004 | |
| | | | First Named Inventor | Jun FENG | |
| | | | Group Art Unit | 1624 | |
| | | | Examiner Name | Thomas C. McKenzie | |
| Sheet | 5 | of | 14 | Attorney Docket Number | SYR-DPP-IV-5004-C2 |

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| Sheet 6 of 14 | Attorney Docket Number | | SYR-DPP-IV-5004-C2 |

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| | | First Named Inventor | Jun FENG | | |
| | | Group Art Unit | 1624 | | |
| | | Examiner Name | Thomas C. McKenzie | | |
| Sheet | 7 | of | 14 | Attorney Docket Number | SYR-DPP-IV-5004-C2 |

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| | | First Named Inventor | Jun FENG |
| | | Group Art Unit | 1624 |
| | | Examiner Name | Thomas C. McKenzie |
| Sheet 8 of 14 | Attorney Docket Number | SYR-DPP-IV-5004-C2 | |

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| | LG | WO 03/040114 | 5/15/2003 | BRISTOL-MYERS SQUIBB COMPANY | | |
| | LH | WO 03/051848 | 6/26/2003 | FERRING BV | | |
| | LI | WO 03/053330 | 3/7/2003 | ASTRAZENECA AB | | |
| | LJ | WO 03/055881 | 7/10/2003 | F. HOFFMANN-LA ROCHE AG | | |
| | LK | WO 03/057144 | 7/17/2003 | GUILFORD PHARMACEUTICALS | | |
| | LL | WO 03/057666 | 7/17/2003 | GUILFORD PHARMACEUTICALS | | |
| | LM | WO 03/065983 | 8/14/2003 | MERCK & CO., INC. | | |
| | LN | WO 03/068748 | 8/21/2003 | F. HOFFMANN-LA ROCHE AG | | |
| | LO | WO 03/068757 | 8/21/2003 | F. HOFFMANN-LA ROCHE AG | | |
| | LP | WO 03/072197 | 9/4/2003 | PFIZER PRODUCTS INC. | | |
| | LQ | WO 03/074500 | 9/12/2003 | SANOFI-SYNTHELABO | | |
| | LR | WO 03/076393 | 9/18/2003 | NOVARTIS AG | | |
| | LS | WO 03/077935 | 9/25/2003 | IMTM INSTITUT FÜR MEDIZINTECHNOLOGIE MAGDEBURG GMBH, | | |
| | LT | WO 03/080070 | 10/2/2003 | NOVARTIS AG | | |
| | LU | WO 03/080633 | 10/2/2003 | NIPPON KAYAKU KABUSHIKI KAISHA | | |
| | LV | WO 03/082817 | 10/9/2003 | MERCK & CO., INC. | | |
| | LW | WO 03/082859 | 10/9/2003 | NOVARTIS AG | | |
| | LX | WO 03/084940 | 10/16/2003 | SANKARANARAYANAN, Alangudi | | |
| | LY | WO 03/101449 | 12/11/2003 | PFIZER PRODUCTS INC. | | |
| | LZ | WO 03/101958 | 12/11/2003 | PFIZER PRODUCTS INC. | | |
| | MA | WO 03/104207 | 12/18/2003 | MERCK & CO., INC. | | |
| | MB | WO 03/104208 | 12/18/2003 | MERCK & CO., INC. | | |
| | MC | WO 03/104229 | 12/18/2003 | EISAI CO., LTD. | | |

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| Examiner Signature | | Date Considered | |
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| | | Application Number | 10/809,637 | | |
| | | Filing Date | March 24, 2004 | | |
| | | First Named Inventor | Jun FENG | | |
| | | Group Art Unit | 1624 | | |
| | | Examiner Name | Thomas C. McKenzie | | |
| Sheet | 11 | of | 14 | Attorney Docket Number | SYR-DPP-IV-5004-C2 |

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|--|----|--------------|------------|---|--|--|
| | MD | WO 03/106456 | 12/24/2003 | SANOFI-SYNTHELABO | | |
| | ME | WO 04/002535 | 1/8/2004 | HORMOS MEDICAL CORPORATION | | |
| | MF | WO 04/002986 | 1/8/2004 | BANYU PHARMACEUTICAL CO., LTD. | | |
| | MG | WO 04/004655 | 1/15/2004 | BRISTOL-MYERS SQUIBB COMPANY | | |
| | MH | WO 04/004661 | 1/15/2004 | POINT THERAPEUTICS, INC. | | |
| | MI | WO 04/004665 | 1/15/2004 | BRISTOL-MYERS SQUIBB COMPANY | | |
| | MJ | WO 04/007446 | 1/22/2004 | YAMANOUCHI PHARMACEUTICAL CO., LTD. | | |
| | MK | WO 04/007468 | 1/22/2004 | MERCK & CO., INC. | | |
| | ML | WO 04/011640 | 2/5/2004 | TANABE SEIYAKU CO., LTD. | | |
| | MM | WO 04/014860 | 2/19/2004 | TAKEDA CHEMICAL INDUSTRIES, LTD. | | |
| | MN | WO 04/018467 | 3/4/2004 | BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG | | |
| | MO | WO 04/018468 | 3/4/2004 | BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG | | |
| | MP | WO 04/018469 | 3/4/2004 | BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG | | |
| | MQ | WO 04/020407 | 3/11/2004 | TAISHO PHARMACEUTICAL CO., LTD. | | |
| | MR | WO 04/024184 | 3/25/2004 | TAKEDA CHEMICAL INDUSTRIES, LTD. | | |
| | MS | WO 04/026822 | 4/1/2004 | ABBOTT LABORATORIES | | |
| | MT | WO 04/028524 | 4/8/2004 | EISAI CO., LTD. | | |
| | MU | WO 04/031175 | 4/15/2004 | BANYU PHARMACEUTICAL CO., LTD. | | |
| | MV | WO 04/032836 | 4/22/2004 | MERCK & CO., INC. | | |
| | MW | WO 04/032861 | 4/22/2004 | BRISTOL-MYERS SQUIBB COMPANY | | |
| | MX | WO 04/033455 | 4/22/2004 | NOVO NORDISK A/S | | |
| | MY | WO 04/037169 | 5/6/2004 | MERCK & CO., INC. | | |
| | MZ | WO 04/037181 | 5/6/2004 | BRISTOL-MYERS SQUIBB COMPANY | | |
| | NA | WO 04/041795 | 5/21/2004 | GUILFORD PHARMACEUTICALS INC. | | |
| | NB | WO 04/043940 | 5/27/2004 | MERCK & CO., INC. | | |
| | NC | WO 04/046106 | 6/3/2004 | PFIZER PRODUCTS INC., | | |

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|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
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| | | Application Number | 10/809,637 |
| | | Filing Date | March 24, 2004 |
| | | First Named Inventor | Jun FENG |
| | | Group Art Unit | 1624 |
| Examiner Name | Thomas C. McKenzie | | |
| Sheet 12 of 14 | Attorney Docket Number | | SYR-DPP-IV-5004-C2 |

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|----|--------------|------------|---|--|--|
| ND | WO 04/048352 | 6/10/2004 | FUJISAWA PHARMACEUTICAL CO., LTD. | | |
| NE | WO 04/050022 | 6/17/2004 | MERCK & CO., INC. | | |
| NF | WO 04/050656 | 6/17/2004 | EISAI CO., LTD. | | |
| NG | WO 04/050658 | 6/17/2004 | BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG | | |
| NH | WO 04/052850 | 6/24/2004 | BRISTOL-MYERS SQUIBB COMPANY | | |
| NI | WO 04/058266 | 7/15/2004 | MERCK & CO., INC. | | |
| NJ | WO 04/064778 | 8/5/2004 | MERCK & CO. INC. | | |
| NK | WO 04/067509 | 8/12/2004 | SANWA KAGAKU KENKYUSHO CO., LTD. | | |
| NL | WO 04/069162 | 8/19/2004 | MERCK & CO., INC. | | |
| NM | WO 04/071454 | 8/26/2004 | GUILFORD PHARMACEUTICALS INC. | | |
| NN | WO 04/075815 | 9/10/2004 | AVENTIS PHARMA DEUTSCHLAND GMBH | | |
| NO | WO 04/075891 | 9/10/2004 | AVENTIS PHARMA DEUTSCHLAND GMBH | | |
| NP | WO 04/076401 | 9/10/2004 | AVENTIS PHARMA DEUTSCHLAND GMBH | | |
| NQ | WO 04/076433 | 9/10/2004 | AIC | | |
| NR | WO 04/076434 | 9/10/2004 | AIC | | |
| NS | WO 04/078777 | 9/16/2004 | BIOREXIS PHARMACEUTICAL CORPORATION | | |
| NT | WO 04/080958 | 9/23/2004 | MERCK & CO. INC. | | |
| NU | WO 04/083212 | 9/30/2004 | MERCK & CO., INC. | | |
| NV | WO 04/085661 | 10/7/2004 | MERCK & CO., INC. | | |
| NW | WO 04/087053 | 10/14/2004 | SYRRX, INC. | | |
| NX | WO 04/087650 | 10/14/2004 | MERCK & CO. INC. | | |
| NY | WO 04/087880 | 10/14/2004 | BAYER PHARMACEUTICALS CORPORATION | | |
| NZ | WO 04/089362 | 10/21/2004 | NOVO NORDISK A/S | | |
| OA | WO 04/096806 | 11/11/2004 | SUMITOMO PHARMACEUTICALS CO. LTD. | | |
| OB | WO 04/098625 | 11/18/2004 | PROBIODRUG AG | | |
| OC | WO 04/099134 | 11/18/2004 | PROSIDION LTD. | | |
| OD | WO 04/099185 | 11/18/2004 | FUJISAWA PHARMACEUTICAL CO. LTD. | | |
| OE | WO 04/101514 | 11/25/2004 | TAISHO PHARMACEUTICAL CO., LTD. | | |
| OF | WO 04/103276 | 12/2/2004 | MERCK & CO., INC. | | |
| OG | WO 04/103993 | 12/2/2004 | SYRRX, INC. | | |

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| Examiner Signature | | Date Considered | |
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| | | Filing Date | March 24, 2004 | | |
| | | First Named Inventor | Jun FENG | | |
| | | Group Art Unit | 1624 | | |
| | | Examiner Name | Thomas C. McKenzie | | |
| Sheet | 13 | of | 14 | Attorney Docket Number | SYR-DPP-IV-5004-C2 |

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|--|----|----------------|------------|---|--|--|
| | OH | WO 04/110436 | 12/23/2004 | MERCK & CO., INC. | | |
| | OI | WO 04/111041 | 12/23/2004 | FUJISAWA PHARMACEUTICAL CO., LTD. | | |
| | OJ | WO 04/111051 | 12/23/2004 | BOEHRINGER INGELHEIM INTERNATIONAL GMBH | | |
| | OK | WO 04/112701 | 12/29/2004 | MERCK & CO., INC. | | |
| | OL | WO 05/000846 | 1/6/2005 | F.HOFFMANN-LA ROCHE AG | | |
| | OM | WO 05/003135 | 1/13/2005 | MERCK & CO., INC. | | |
| | ON | WO 05/011581 | 2/10/2005 | MERCK & CO., INC. | | |
| | OO | WO 05/012249 | 2/10/2005 | BRISTOL-MYERS SQUIBB COMPANY | | |
| | OP | WO 05/019168 | 3/3/2005 | PFIZER PRODUCTS INC. | | |
| | OQ | WO 2005/016911 | 2/24/2005 | Syrrx, Inc. | | |

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS | | | |
|--|-----------------------|---|--|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | |
| | OR | Database Crossfire Beilstein Institut zur Foerderung der Wissenschaften, Frankfurt am Main, DE; XP002335064. Database Accession no. 1447881 & J. HETEROCYCL.CHEM., Vol. 305, 1972, pages 724-730. | |
| | OS | Database Crossfire Beilstein Institut zur Foerderung der Wissenschaften, Frankfurt am Main, DE; XP002335065. Database Accession no. 1447134 & J.ORG.CHEM., Vol. 43, 1978, pages 4069-4074. | |
| | OT | Database Crossfire Beilstein Institut zur Foerderung der Wissenschaften, Frankfurt am Main, DE; XP002335066. Database Accession no. 386682 & J.CHEM.SOC., 1952, pages 4985-4990. | |
| | OU | Database Crossfire Beilstein Institut zur Foerderung der Wissenschaften, Frankfurt am Main, DE; XP002335067. Database Accession no. 389575 & CHEM.BER., Vol. 88, 1968, pages 106-109. | |
| | OV | Database Crossfire Beilstein Institut zur Foerderung der Wissenschaften, Frankfurt am Main, DE; XP002335068. Database Accession no. 472441 & YAKUGAKU ZASSHI, Vol. 88, 1968, pages 106-109. | |
| | OW | Database Crossfire Beilstein Institut zur Foerderung der Wissenschaften, Frankfurt am Main, DE; XP002335069. Database Accession no. 1447840 & CHEM.BER., Vol. 101, No. 8, 1968, pages 2679-2689. | |
| | OX | Database Crossfire Beilstein Institut zur Foerderung der Wissenschaften, Frankfurt am Main, DE; XP002335070. Database Accession no. 1448669 & CHEM.BER., Vol. 101, No. 8, 1968, pages 2679-2689. | |
| | OY | Database Crossfire Beilstein Institut zur Foerderung der Wissenschaften, Frankfurt am Main, DE; XP002335071. Database Accession no. 4991064, J.CHEM.SOC.PERKIN TRANS.1, 1980, pages 1370-1380. | |

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| | | Filing Date | March 24, 2004 |
| | | First Named Inventor | Jun FENG |
| | | Group Art Unit | 1624 |
| | | Examiner Name | Thomas C. McKenzie |
| Sheet 14 of 14 | Attorney Docket Number | SYR-DPP-IV-5004-C2 | |

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| OZ | Database Crossfire Beilstein Institut zur Foerderung der Wissenschaften, Frankfurt am Main, DE; XP002335072. Database Accession no. 990008, J.PRAKT.CHEM., Vol. 315, 1973, pages 1166-1168. | |
| PA | Database Crossfire Beilstein Institut zur Foerderung der Wissenschaften, Frankfurt am Main, DE; XP002335073. Database Accession no. 6219070, J.PRAKT.CHEM., Vol. 330, No. 2, 1988, pages 323-324. | |
| PB | Database Crossfire Beilstein Institut zur Foerderung der Wissenschaften, Frankfurt am Main, DE; XP002335074. Database Accession no. 392446, J.HETEROCYCL.CHEM., Vol. 8, 1971, pages 367-371. | |
| PC | Database Crossfire Beilstein Institut zur Foerderung der Wissenschaften, Frankfurt am Main, DE; XP002335075. Database Accession no. 4742608, J. PRAKT.CHEM., Vol. 333, No. 1, 1991, pages 149-151. | |
| PD | Database Crossfire Beilstein Institut zur Foerderung der Wissenschaften, Frankfurt am Main, DE; XP002335076. Database Accession no. 490809, & ANGEW.CHEM., Vol. 84, 1972, page 1185. | |
| PE | Database Crossfire Beilstein Institut zur Foerderung der Wissenschaften, Frankfurt am Main, DE; XP002335063. Database Accession no. 1525341 & J. HETEROCYCL.CHEM., Vol. 12, 1975, pages 683-687. | |
| PF | GUPTA, A. et al.: "Fluorine containing Biologically Active Agents: Synthesis of some new Pyrimidine Derivatives" J.IND. CHEM.SOC., Vol. 71 1994, pages 635-636, XP000889664 compound 1 | |
| PG | Kesarwani, A. P. et al.: Solid-phase synthesis of quinazolin-(3H)-ones with three-point diversity, Tetrahedron Letters, Vol. 43, (2002) pp. 5579-5581. | |
| PH | Rauchman, B.S. et al. "2,4-Diamino-5-benzylpyrimidines and Analogues as antibacterial Agents", Journal of Med. Chem., Vol. 23, 1980, pages 384-391, XP002335048 Scheme II | |

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| Examiner Signature | | Date Considered | |
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